II. REMARKS

Claims 1-19 and 21 and 23-30 were pending in the parent application. Claims 1-18 have been withdrawn pursuant to a restriction requirement. Claims 19, 21, 23 and 25-30 were variously rejected under 35 U.S.C. §§ 102 and 103. Claim 24 was allowable and objected to for being dependent from a rejected base claim.

The claims have been amended herein and are now directed to subject matter that the Office has indicated is allowable, namely LT-R72. Applicants reserve the right to file a continuation or divisional application directed to the subject matter of previous claims at any time during the pendency of this application.

The specification has been amended to include an additional Figure showing the amino acid sequence of a wild-type LT-A, as disclosed in Domenighini et al. (1995) *Mol Microbiology* 15(6):1165-1167 (submitted herewith in an Information Disclosure Statement). Also submitted herewith is a revised sequence listing. The reference, and the sequence contained therein, was published two years prior to the priority date of the present application and accordingly, introduction of this sequence does not constitute new matter. Further, Applicants direct the Examiner's attention to the last paragraph beginning on page 3 where the specification indicates that "it is accepted in the art that CT and LT are generally interchangeable, showing considerable homology... ." In this regard, Applicants note that the wild-type LT-A sequence shown in Figure 3 is highly homologous to CT of Figure 1.

No new matter has been added as a result of any of these amendments and entry thereof is respectfully requested.

In view of the foregoing amendments and the Office's acknowledgment that the amended claims define an invention that is free of the prior art as well as described and enabled by the specification, Applicants submit that the claims are now in condition for allowance and request early notification to that effect.

Please direct all further communications regarding this application to:

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Respectfully submitted,

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Marked-Up Copy of the Specification

On page 6, line 3 the following paragraph has been inserted:

--**Figure 3** (SEQ ID NO:5) shows the amino acid sequence of a wild-type LT-A.--

Version Showing Changes Made to Claims

19. (Amended) A method for immunizing a vertebrate subject against at least one selected antigen, the method comprising the step of parenterally administering to the vertebrate subject an immunologically effective amount of

a) a parenteral adjuvant comprising a detoxified mutant of an *E. coli* heat-labile toxin (LT) ADP-ribosylating toxin [selected from the group consisting of LT-R72 and LT-K63] in combination with a pharmaceutically acceptable vehicle, wherein said detoxified mutant is LT-R72; and

b) at least one selected antigen.

23. Canceled.

24. Canceled.

Currently Pending Claims

19. (Amended) A method for immunizing a vertebrate subject against at least one selected antigen, the method comprising the step of parenterally administering to the vertebrate subject an immunologically effective amount of

a) a parenteral adjuvant comprising a detoxified mutant of an *E. coli* heat-labile toxin (LT) ADP-ribosylating toxin in combination with a pharmaceutically acceptable vehicle, wherein said detoxified mutant is LT-R72; and

b) at least one selected antigen.

20. Canceled.

21. (Amended) A method according to claim 19 wherein the detoxified mutant comprises one or more amino acid additions, deletions or substitutions in the A subunit of the bacterial toxin.

22 to 24. Canceled.

25. (Amended) A method according to claim 19, wherein the adjuvant and the antigen are administered subcutaneously, transcutaneously or intramuscularly.

26. A method according to claim 19, wherein the pharmaceutically acceptable vehicle is a topical vehicle.

27. A method according to claim 26, wherein the adjuvant and the antigen are administered transcutaneously.

28. A method according to claim 19, wherein the adjuvant is administered to the vertebrate subject prior to administering the selected antigen.

29. A method according to claim 19, wherein the adjuvant is administered to the vertebrate subject subsequent to administering the selected antigen.

30. A method according to claim 19, wherein the antigen is administered to the vertebrate subject concurrent with administering the selected antigen.

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NGDRLYRADS RPPDEIKRSG GLMPRGHNEY FDRGTQMNIN LYDHARGTQT    50
GFVRYDDGYV STSLSLRSAH LAGQSILSGY STYYIYVIAT APNMFNVNDV   100
LGVYSPHPYE QEVSALGGIP YSQIYGWYRV NFGVIDERLH RNREYRDRYY   150
RNLNIAPAED GYRLAGFPPD HQAWREEPWI HHAPQGCGNS SRTITGDTCN   200
EETQNLSTIY LREYQSKVKR QIFSDYQSEV DIYNRIRDEL              240
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FIGURE 3